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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,795	02/22/2002	Fredrik Kamme	PRI-0021 (ORT-1508)	9944
23377	7590	10/06/2003	EXAMINER	
WOODCOCK WASHBURN LLP ONE LIBERTY PLACE, 46TH FLOOR 1650 MARKET STREET PHILADELPHIA, PA 19103			KIM, YOUNG J	
			ART UNIT	PAPER NUMBER
			1637	12

DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/080,795

Applicant(s)

KAMME ET AL.

Examiner

Young J. Kim

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 July 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

The Examiner of the instant application has been changed. All further correspondence regarding this application should be directed to Examiner Young J. Kim whose Group Art Unit is 1637.

The present Office Action responds the Amendment received on July 23, 2003 (Paper No. 10).

#### *Drawings*

The objection to the drawing, more particularly, Figures 1 and 2, for poor resolution of the bands in the electrophoresis gel, made in the Office Action mailed on April 23, 2003, is withdrawn for the following reasons.

For the initial matter, Applicants contend that the previous Examiner did not “explain the basis for the objection.” (page 9, Response). To the contrary, the previous Examiner **did** point out, in page 2, paragraph 3, that the drawings were objected to because the photographs of the gel electrophoresis illustrated *poor resolution of the bands*.

However, upon perusal of the Figures, the present Examiner recognizes that the smearing of the bands is customary in RNA samples, and therefore the objection is hereby **withdrawn**.

#### *Specification*

The objection to the specification for the use of the trademark Superscript II has been noted in this application (on page 29, line 5), made in the Office Action mailed on April 23, 2003 is maintained for the reasons of record. The trademark should be capitalized wherever it appears and be *accompanied by the generic terminology*.

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Applicants again appear to contend that the previous Examiner failed to address basis of the objection. To the contrary, the basis of the objection has been *clearly* presented in the previous Office Action (see page 3, paragraph 4) mailed on April 23, 2003, wherein the Office Action states that the specification is objected to for, “[t]he use of trademark ‘Superscript’ (page 29, line 5).” Applicants’ attention is directed to section 608.01(v) of MPEP.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The rejection of claims 3, 6, 15, and 25 under 35 U.S.C. 102(e) as being clearly anticipated by Linsley et al. (U.S. Patent No. 6,271,002 B1, issued August 7, 2001, filed October 4, 1999), made in the Office Action mailed on April 23, 2003 is withdrawn in view of the Amendment received on July 23, 2003, amending the claims to be exclusively drawn to a method using a Bst DNA Polymerase.

### ***Rejection - Maintained***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The rejection of claims 1, 2, 4, 5, 7-14, 16-24, and 26 under 35 U.S.C. 102(a) as being clearly anticipated by Linsley et al. (U.S. Patent No. 6,271,002 B1, issued August 7, 2001, filed

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October 4, 1999), made in the Office Action mailed on April 23, 2003 is maintained for the reasons of record.

Applicants' arguments received on July 23, 2003 have been fully considered but they are not found persuasive for the following reasons.

Applicants' arguments are addressed in the order they were presented.

Applicants argue that Linsley et al. fail to teach or suggest a method or kit for synthesizing a second strand of DNA by contacting a thermostable DNA polymerase with a thermostable RNase H under conditions conducive to thermostable DNA polymerase activity (page 10, Resposne).

To the contrary, Linsley et al. do teach *and* suggest a method/kit for synthesizing a second strand of DNA by combination of a thermostable DNA polymerase (Taq polymerase) and an RNase H (column 15, lines 50-59; Figure 1). Since the amplification of the double stranded DNA is subject amplification via Taq polymerase, arguably, the first strand DNA is contacted with Taq polymerase to generate a second strand DNA (or its complement).

Applicants also argue that Linsley et al. disclose an incubation temperature (of second strand DNA) far below the claimed temperature range of 45-80°C (page 11, Response). This is not true since Linsely et al. do disclose that the second strand synthesis occurs between 37 and 55°C which is within the claimed range.

Therefore, for the reasons above, the invention as claimed is anticipated by Linsley et al.

***Claim Rejections - 35 USC § 103 – Necessitated by Amendment***

The following rejection is necessitated by Applicants amendment to claims 3, 6, 15, and 25, amending the claims to make the claimed inventions exclusively drawn to method/kit using a Bst DNA polymerase.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 6, 15, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Linsley et al. (U.S. Patent No. 6,271,002 B1, issued August 7, 2001, filed October 4, 1999) in view of Gu et al. (U.S. Patent No. 6,436,677 B1, issued August 20, 2002, filed March 2, 2000).

Linsley et al. disclose a method of generating a cRNA from RNAs extracted from a mammalian cell (column 3, line 61; column 14, lines 20-27), via use of thermostable DNA polymerase (Figure 1) and RNase H (column 15, lines 50-59). The cRNA disclosed by Linsley et al. is differentially labeled by fluorescent labels such as Cy3 and Cy5 (column 7, line 24; column 13, lines 19-21) and hybridized on the array (column 20, line 49) comprising at least 1,000, more particularly, at least 2,000 different probes (column 22, lines 10-15) for the purpose of comparing gene expression between different populations of cells, wherein the populations of cells are diseased and normal (column 5, line 50).

Linsley et al. do not disclose the method/kit utilizing exclusively Bst DNA polymerase for the second strand synthesis of cDNA synthesis.

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Gu et al. disclose a method of generating a second strand cDNA from an RNA molecule by use of a thermostable Bst DNA polymerase (column 29, lines 50-57), for the purpose of detection of target sequences.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Linsley et al. with that of Gu et al. to arrive at the invention as claimed because by doing so, one of ordinary skill in the art would have been able to generate, "high fidelity cDNA" (column 1, line 61) for the purpose of target detection. It is a well-known desire to one of ordinary skill in the art to be able to reduce errors in amplifying target nucleic acid molecules by employing high fidelity polymerases. Therefore, with the teachings of Gu et al. and the well-known desire in the art, one of ordinary skill in the art would have had a reasonable expectation of success in substituting the thermostable DNA polymerase of Linsley et al. with that of Gu et al.

Therefore, the invention as claimed is obvious over the cited references.

### ***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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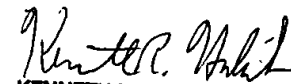
the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### *Inquiries*

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (703) 308-9348. The Examiner can normally be reached from 8:30 a.m. to 7:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (703)-308-3905. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (703) 872-9306. For Unofficial documents, faxes can be sent directly to the Examiner at (703) 746-3172. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Young J. Kim

10/1/03

  
KENNETH R. HORLICK, PH.D.  
PRIMARY EXAMINER

10/2/03